

11/19/98

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November 10,1998

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Supports the Digestive Process** 

Papain from papaya and Bromelain from pineapple contain natural enzymes. Enzymes play a role in the breakdown of food in the body.

on the following product:

Tree of Life® Digestive Enzyme Blend (Papaya & Bromelain)

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs

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